REMARKS

I. Status of the Claims

Claim 15 has been amended to reword the phrase pertaining to the drug microparticles, and to clarify that the first layer consists essentially of ethylcellulose. Support for the latter amendment may be found throughout the specification, particularly at page 4, lines 4-29. Additionally, claim 15 has been amended to clarify that the acrylic polymer is soluble at acidic pH. Support for the latter amendment may be found at the very least at page 5, line 24 and page 8, line 23. Claim 23 has been amended to clarify that the drug potency is between 400 mg drug/g of microcapsules and 950 mg drug/g of microcapsules. Support for the claim amendment may be found on page 5, lines 31-32. New claims 40-41 have been added and further define the nature of the acrylic polymer. Support for these claims may be found at page 5, lines 24-27. No prohibited new matter is believed to have been added. Claims 15-41 are now pending. Claims 15-28 and 40-41 are under examination, and claims 29-39 are withdrawn.

II. Rejection under 35 U.S.C. §112, first paragraph

Claims 15-28 were rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. Essentially, the Examiner believes that the use of the term "comprising" with reference to the microparticles in claim 15 expands the scope of the claim beyond what is described in the specification. Without agreeing with the rejection, Applicants have rephrased the claim to refer to "drug microparticles" instead of "microparticles comprising drug." Nevertheless, Applicants respectfully disagree with the rejection since the specification makes it clear that the invention pertains to a microcapsule formulation comprising any of a wide variety of drug microparticles and methods of making the same. The skilled artisan would readily appreciate that the drug microparticles in the compositions of the claimed invention may be made using any technique known in the art, using any suitable ingredients, excipients, etc., so long as the microcapsule composition contains the specific layers specified in the claims.

III. Rejection under 35 U.S.C. §112, second paragraph

Claim 23 was rejected under 35 U.S.C. §112, second paragraph because the units mg/g is allegedly unclear. Without agreeing with the rejection, Applicants have amended claim 23 to clarify that the potency is between 400 mg drug/g of microcapsules and 950 mg drug/g of microcapsules. Reconsideration and withdrawal of the rejection are respectfully requested.

IV. Rejections under 35 U.S.C. §102

Claims 15-24 and 26-28 were rejected under 35 U.S.C. §102(e) as being allegedly anticipated by Percel (US 6,451,345). Without agreeing with the rejection, Applicants note that claim 15 as amended above specifies that the acrylic polymer is soluble at acidic pH. See also new claims 40 and 41 which specify that the acrylic polymer is soluble in 1N HCl and that the acrylic polymer is Eudragit E, respectively. The present claims are distinguishable over the disclosure of Percel in that the claimed compositions employ acrylic polymers which are soluble at acidic pH as exemplified by the reverse enteric polymer Eudragit E. In contrast, Percel exemplifies using enteric polymers Eudragit L and S, which are soluble at higher pH and relatively insoluble at lower pH. Reconsideration and withdrawal of the §102 rejection based on Percel are respectfully requested.

Claims 15-17, 19-20 and 23-28 were rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Holt et al. (WO 00/30617). Without agreeing with the rejection, Applicants note that claim 15 as amended above specifies that the first layer disposed over the microparticles consists essentially of ethylcellulose. Holt does not teach a first layer consisting essentially of ethylcellulose. Rather, Holt employs an ethylcellulose polymer (PVP or HPMC) blend. Both PVP and HP MC are well known in the pharmaceutical arts as water-soluble polymers, and as such would reasonably be expected to materially affect the properties of a pharmaceutical coating containing such polymers, e.g. by dissolving upon ingestion and enhancing dissolution of the drug coated thereby. Accordingly, as amended, the present claims would exclude the ethylcellulose/PVP or HPMC blends of Holt. Reconsideration and withdrawal of the §102 rejection based on Holt are respectfully requested.

V. Rejections under 35 U.S.C. §103

Claims 15-24 and 26-28 were rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Percel. Essentially, the Examiner admits that the range of wt% of acrylate polymer coating and the size range of Percel's microcapsule differ from that recited in claims 18 and 22, respectively. Nevertheless, the Examiner believes that a person of ordinary skill in the art would reach the claimed ranges through customary optimization. Applicants note, however, that the claims as amended are directed to microcapsule compositions wherein the second layer comprises an acrylic polymer that is soluble in acidic pH. This differs from the second layer exemplified by Percel. Furthermore, there is nothing in the specification of Percel to direct the skilled artisan to try using such an acrylic polymer. Accordingly, reconsideration and withdrawal of the §103 rejection based on Percel are respectfully requested.

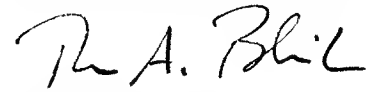
Claims 15-28 were rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Holt. Again, the Examiner admits that the range of wt% of acrylate polymer coating and the size range of Holt's formulation differ from that recited in claims 18, 21 and 22. Nevertheless, the Examiner believes that a person of ordinary skill in the art would reach the claimed ranges through customary optimization. Applicants note, however, that the claims as amended are directed to microcapsule compositions wherein the first layer consists essentially of ethylcellulose. Although Holt includes ethylcellulose in a laundry list of materials to use for the first layer (see page 10), Holt provides no direction for using ethylcellulose alone and only exemplifies using ethylcellulose blended with a water soluble polymer. See, e.g., MPEP 2163 (citing *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species). In light of the above remarks, reconsideration and withdrawal of the §103 rejection based on Holt are respectfully requested.

Except for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this

application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-1283. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. 1.136(a)(3).

Dated: August 27, 2009

Respectfully submitted,
COOLEY GODWARD KRONISH LLP

By: 

Thomas A. Blinka
Reg. No. 44,541

COOLEY GODWARD KRONISH LLP
CUSTOMER NUMBER 58249
ATTN: Patent Group
777 6th Street, NW, Suite 1100
Washington, DC 20001
Tel: (202) 842-7800
Fax: (202) 842-7899